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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/874,318	06/06/2001	Otmar Klingler	02481.1747	6154

7590 01/28/2002

Finnegan, Henderson, Farabow,  
Garrett & Dunner, L.L.P.  
1300 I Street, N.W.  
Washington, DC 20005-3315

EXAMINER

COVINGTON, RAYMOND K

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 01/28/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.  
09/874,318

Applicant(s)  
Klingler et al

Examiner  
Raymond Covington

Art Unit  
1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 6/6/01
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☒ All b) ☐ Some\* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

### Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 4
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Klingler et al US 5,703,050 taken with Tjoeng et al US 5,314,902.

Klingler et al '050 carbamimido-phenylurea derivatives of the type recited in the claims and their use as thrombocyte inhibitors. See for example column 1 lines 30-58 particularly where  $R^1$  is  $-C(=NX)-NH_2$ , A is  $-phenylene-N-$ , n and p = 0, W is  $-COW^1$  or tetrazolyl, column 2 lines 15+ line 35 in particular, and the preferred embodiment column 9 lines 15+. While an express example of all of the possible species is not disclosed the claimed invention as a whole would have been obvious to one of ordinary skill in the art particularly in view of Tjoeng et al which teach analogous derivatives. See, for example, column 2 lines 10+ and column 3 line 1-44. Note m is most preferably =0 and R can be hydrogen. In view of the above other structurally closely related derivatives would have been obvious as the result thrombin inhibition, would not have been unexpected.

Claim 11 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for inhibiting factor VIIa does not reasonably provide enablement for treating cardiovascular disorders, thromboembolic diseases or restenoses. The

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specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The specification does not give any guidance as to the full range of conditions which could be treated using the instant claimed process. In *In re Wands*, 8 USPQ2d 1400 (1988), factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. § 112, first paragraph, have been described.

They are:

1. the nature of the invention,
2. the state of the prior art,
3. the predictability or lack thereof in the art,
4. the amount of direction or guidance present,
5. the presence or absence of working examples,
6. the breadth of the claims,
7. the quantity of experimentation needed, and
8. the level of the skill in the art.


In the instant case, Applicants are claiming a method of treating cardiovascular disorders, thromboembolic diseases or restenoses. The nature of the pharmaceutical arts

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is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired pharmacological activities. There is no absolute predictability even in view of the seemingly high level of skill in the art. The existence of these obstacles establishes that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any therapeutic regimen on its face. In the instant specification, applicants on page 73 of the specification show only how antithrombotic efficacy can be assessed. The disclosure does not show that claimed invention actually has any efficacy. Nor is there sufficient disclosure to support the claimed methods of use.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Raymond Covington whose telephone number is (703)308-4704.

  
Covington/LR

January 8, 2002

  
ALAN L. ROTMAN  
PRIMARY EXAMINER  
SPE A.V. 1625